

*The guidelines available here use language posted in the original funding opportunity announcement (FOA) and do not replace or modify the criteria established in the full announcement. If you have any questions, contact the Scientific Review Officer (SRO) in charge of the review panel. SRO contact information for your application can be found in [eRA Commons](#).*

## REVIEWER GUIDELINES

### NIDDK P01 PROGRAM PROJECTS

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## **INSTRUCTIONS FOR PREPARATION OF P01 CRITIQUES**

Please bring a laptop to the meeting, unless the meeting is via teleconference. Should you need to make some minor edits to your critiques you will be able to do so before the meeting concludes. You may upload any final edits into the Internet Assisted Review System after the meeting. Each reviewer is expected to read the complete application.

You will all comment on the merit of the entire Program Project as a whole and will need to be familiar with the entire application. A key point to remember is that beyond the scores assigned to each project and core, a single score is assigned to the entire Program Project as a whole. It is the "Overall Score" that will be used to guide the Program staff of the NIDDK and our National Advisory Council in their funding recommendations. The Overall Score is not just an average of the scores assigned to the projects and cores. It requires that you factor in whether there is synergy and cohesiveness between the individual components. Is the whole greater than the sum of the parts? Are the projects simple stand alone R01 type applications or together will they achieve something more by being combined with each other in a program? Does the Principal Investigator have sufficient experience and skill to lead a program of this size and complexity?

### **Introduction - General Review Considerations**

At least three projects must extend for the duration of the program project. Each project will be assigned a separate priority score, taking into consideration only its merit as an individual research project. It is important that each project fits and contributes to the theme of the overall program project, but this factor should be judged separately and have no bearing on a project's individual priority score. Instead, these considerations will be addressed later with respect to the merit of the overall program project.

It is expected that individual components, in order to receive funding, will not represent significantly poorer research than is being funded by the R01 mechanism. A project whose score is somewhat poorer than currently funded R01 grants may benefit greatly from inclusion in the overall program project, whereby synergism with other components and use of core facilities significantly enhance its value. Conversely, such a project might provide certain elements that greatly enhance other projects in the overall program project. Such considerations would be expected to have impact on the overall priority score assigned by the reviewers to the program project.

ALL projects and cores must be scored in order for the overall program project to be assigned a priority/impact score. Reviewers should utilize the full score range as appropriate, and discuss all projects and cores. Projects or cores may *not* be selectively not recommended (deleted) in order to improve an application's overall priority/impact score.

It is important to consider the contribution of the cores to each project in both scientific and budget terms.

All applications except supplements must request and be reviewed for 5 years of project period support. While one or more projects may be recommended for less than 5 years, only in very unusual circumstances may the entire program project be recommended for less than 5 years.

In the case of the review of a competing continuation (renewal) application, the progress made during the past period of funding is also an important consideration in the review of projects and cores.

Scientific or budgetary overlap, if identified in an application, should be noted in a statement separate from the critique and should not be considered in the evaluation of the scientific merit of the application. The Scientific Review Administrator will ensure that such issues are documented in the summary statement as an administrative note. Purported overlap must be resolved by NIH staff before an award is made.

Note that the following guidelines are taken from the NIDDK P01 FOA ([http://grants.nih.gov/grants/guide/pa-files/PAR-13-266.html#\\_Section\\_V\\_Application](http://grants.nih.gov/grants/guide/pa-files/PAR-13-266.html#_Section_V_Application)) but are re-ordered to follow the order of review that normally occurs.

## Review of Individual Projects

**Overall Evaluation:** Briefly summarize the most important points of your critique, weighting the review criteria as you feel appropriate. Evaluate the overall impact on the field. It is important that each project fits and contributes to the theme of the overall program project, but this factor should be judged separately and have no bearing on a project's individual impact score. Instead, these considerations are addressed with respect to the merit of the overall program project.

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An project does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

The review criteria for individual research projects are:

**Significance:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Investigator:** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

**Innovation:** Does the project challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children justified in terms of the scientific goals and research strategy proposed?

**Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

**Budget:** If any changes are recommended, provide a justification along with a specific dollar amount. The budget is not considered when you evaluate the scientific merit of the project and does not contribute to the priority score.

## **Review of Individual Cores**

The review criteria for the individual cores are given below. Although cores receive merit descriptors rather than numeric scores, you may enter a numeric score in IAR, which will be converted following the review, and provided in the summary statement. Individual criterion scores are not provided:

### **Review Criteria for Administrative Core**

- Utility of the core to the program project;
- Quality of the facilities or services provided by this core (administrative planning and leadership capability to provide for internal quality control of ongoing research, allocation of funds, enhancement of internal communication and cooperation among the investigators involved in the program, and replacement of the principal investigator/program director if required on an interim or permanent basis);
- Qualifications, experience, and commitment of the personnel involved in the core; and
- Appropriateness of the core in relation to the scope of the proposed administrative support.

### **Review Criteria for Individual Research Cores**

- Utility of the core to the program project; each core must provide essential facilities or service for two or more projects
- Quality of the facilities or services provided by this core (including procedures, techniques, and quality control) and criteria for prioritization of usage;
- Qualifications, experience, and commitment of the personnel involved in the core; and
- Appropriateness of the core in relation to the scope of the proposed research support.
- If human subjects, vertebrate animals, or biohazards are to be used in the core, the adequacy of these sections must be assessed and will be considered in determining the descriptor of the individual core.

### **Additional Review Criteria**

#### **Protections for Human Subjects [Evaluate for each Project or Core where HS are involved.]**

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Human Subjects Protection and Inclusion Guidelines.

#### **Inclusion of Women, Minorities, and Children [Evaluate for each Project or Core where HS are involved.]**

When the proposed program project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

#### **Vertebrate Animals [Evaluate for each Project or Core where VA are involved.]**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific

assessment according to the following five points: 1) proposed use of the animals, and species,

strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

### **Biohazards [Evaluate for each Project or Core where Biohazards are involved.]**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

### **Resubmissions**

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the Program Project.

### **Renewals**

For Renewals, the committee will consider the progress made in the last funding period. Applicants should include:

- Progress and achievements specific to this program project during the past funding period and the evidence through publications, conferences, etc., that collaboration has occurred;
- Evidence that the previous specific aims have been accomplished and that the new research goals are logical extensions of ongoing work;
- Previous performance and estimated use of the core(s); and
- Justification for adding new projects or cores or for deleting components previously supported.

### **Revisions**

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the overall Program Project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

### **Select Agent Research**

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). (see Select Agents and Toxins List:

<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>

### **Resource Sharing Plans**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

## **Review of Overall Program Project**

The Chair of the review panel will prepare the Overall Critique after the meeting concludes using the reviewer critiques for the projects and cores and notes taken during the group discussion of the overall scientific merit of the Program Project. Once all Projects and Cores have been discussed

and scored the entire review committee will participate in a discussion of the overall scientific merit of the Program Project application. The Chair will initiate the discussion by summarizing points heard during the evaluations of each project and core. Next the discussion will be open to the group and each reviewer can add points of emphasis or disagreements to the discussion.

The relationship and contributions of each research component and core to the overall theme of the program project are discussed and evaluated; these points must be clearly and specifically outlined in the summary statement. This will be a separate consideration which is not determined exclusively by the priority scores of the individual projects.

The overall program project application is evaluated considering the projects, supporting cores, and the administrative structure. For a Program Project to receive a priority score, it must consist of at least three priority-scored individual projects for the duration of the proposed Program Project period. Each core must provide essential functions or services for at least two of these projects.

Specific factors to be evaluated in the consideration of the overall program project are as follows:

### **Overall Impact - Overall**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the overall Program Project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following scored review criteria and additional review criteria (as applicable for the overall Program Project proposed).

#### **Scored Review Criteria - Overall**

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, an overall Program Project that by its nature is not innovative may be essential to advance a field.

#### **Significance**

Does the overall Program Project address an important problem or a critical barrier to progress in the field? If the aims of the overall Program Project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

#### **Investigator(s)**

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the overall Program Project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Do(es) the overall Program Project PD/PI(s) have: (a) track record(s) of consistently producing highly significant research publications in one or more of the research areas proposed for the program project; (b) track record(s) demonstrating the ability to effectively and productively manage a large, interdisciplinary project in the proposed research area?

#### **Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

#### **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the overall Program Project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the overall Program Project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Are the approaches proposed in the individual projects and cores complementary?

### **Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

## **Additional Review Criteria - Overall**

As applicable for the overall Program Project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

### **Synergy**

The relationship and contributions of each research component and core to the overall theme of the program project will be discussed and evaluated. In assigning the impact score for the application as a whole, the assessment of scientific synergy (i.e., the extent to which the potential for scientific impact of the proposed program project as a whole is deemed likely to be greater than the sum of its component research projects and cores) should contribute significantly to the overall score. This will include the following:

- Scientific merit of the program as a whole, as well as that of individual projects, and its potential impact on the field;
- Scientific gain of combining the component parts into a program project (beyond that achievable if each project were to be pursued separately);
- Cohesiveness and multidisciplinary scope of the program and the coordination and interrelationship of all individual research projects and cores to the common theme;

### **Principal Investigator**

Leadership and scientific ability of the **PD(s)/PI(s)** and his or her commitment and ability to develop a well-defined central research focus (request of support for sufficient effort to provide effective oversight and administration of the program should be considered); and past accomplishments of the program or a demonstrated ability in mounting similar programs.

### **Final Recommendation**

If the overall program project is judged to have sufficient merit, an impact/priority score will be assigned based on the application's merit as a program project. This score is not the average of the priority scores assigned to the individual components, but should take into account all of the factors described above.